**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF VIRGINIA**
**Richmond Division**

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| **DOUGLAS M. RAY, JR.,** | ) | |
| | ) | |
| **Plaintiff,** | ) | |
| | ) | |
| **v.** | ) | **Civil No. 3:10cv136** |
| | ) | |
| **ALLERGAN, INC., *et al.*,** | ) | |
| | ) | |
| **Defendants.** | ) | |

**DEFENDANT'S SUPPLEMENTAL REPLY MEMORANDUM IN SUPPORT OF RULE 59 MOTION FOR A NEW TRIAL**

Pursuant to the Court's December 15, 2011 Order, defendant Allergan, Inc. ("Allergan"), by counsel, hereby submits the following reply brief as a supplement to its prior briefing in support of its Rule 59 Motion for New Trial (Dkt. No. 227).[1]

## DISCUSSION

Allergan explained in its supplemental brief that federal law preempted Plaintiff's claims as presented and argued at trial. Plaintiff's primary response is a fundamental misreading of *PLIVA, Inc. v. Mensing*, __ U.S. __, 131 S. Ct. 2567, 2575-76 (2011), based on a superficial and mistaken distinction between *Mensing* and *Wyeth v. Levine*, 555 U.S. 555 (2009). That argument and the specific preemption questions this Court asked in its supplemental briefing order are addressed in Parts I-IV of this reply. Allergan also explained in its supplemental brief that Plaintiff's improper arguments during closing require a new trial. Plaintiff responds by largely

[1] Defendant's Supplemental Memorandum in Support of Rule 59 Motion for a New Trial ("Supp. Br.") was filed as Dkt. No. 242. Plaintiff's Response to Defendant's Supplemental Memorandum in Support of Rule 59 Motion for a New Trial ("Supp. Response") was filed as Dkt. No. 243. The primary briefs related to Defendant's Rule 59 Motion were filed as Dkt. Nos. 228 ("Opening Br."), 236, and 238 ("Rule 59 Reply").

repeating the unpersuasive arguments he made in prior briefing. These arguments are addressed in Parts V-VI of this reply.

## I. *Mensing* Governs This Case

The Supreme Court's decision in *Mensing* governs the preemption analysis of the failure-to-warn claims in this case. Plaintiff contends that *Mensing* does not apply because it involved generic drugs, and instead *Wyeth* applies because it involved brand-name drugs. But that **factual** distinction completely ignores the **legal principle** the Supreme Court applied in both cases—which turned not on the generic/brand-name distinction, but on the difference between what the respective federal regulations required in each case.

The Court held in *Mensing* that "[t]he question for 'impossibility' is whether the private party could **independently** do under federal law what state law requires of it." 131 S. Ct. at 2579 (emphasis added). And the Court cited *Wyeth*, 555 U.S. at 573, as support for this statement of the legal standard, explaining that *Wyeth* found "no preemption where the defendant could 'unilaterally' do what state law required." *Mensing*, 131 S. Ct. at 2579. The difference between the two cases was whether federal law prohibited the defendant from independently satisfying its alleged state-law duty to warn.

In *Mensing*, the Court held that the defendants could **not** independently add a warning to their generic drug labels because "CBE changes unilaterally made to strengthen a generic drug's warning label would violate the statutes and regulations requiring a generic drug's label to match its brand-name counterpart's." *Id.* at 2575; *see also id.* at 2578.[2] In *Wyeth*, by contrast, the defendant was free independently to add a warning because "the CBE regulation, 21 CFR

[2] The manufacturers also could not have issued additional warnings through "Dear Doctor" letters because that would have violated the federal requirement that "such letters must be 'consistent with and not contrary to [the drug's] approved … labeling,'" 21 C.F.R. § 201.100(d)(1), and that labeling not be misleading, 21 C.F.R. § 314.50(b)(3). 131 S. Ct. at 2576.

§ 314.70(c)(6)(iii), permitted a brand-name drug manufacturer like Wyeth 'to unilaterally strengthen its warning' without prior FDA approval." *Mensing*, 131 S. Ct. at 2581 (quoting *Wyeth*, 555 U.S. at 573). The reason that the manufacturers in *Mensing* could not use the CBE regulation to independently add a warning to their labels, but the manufacturers in *Wyeth* could, was that the manufacturers in *Mensing* would have violated **other** federal laws if they had added a warning to their labels.

This case clearly falls on the *Mensing* side of the line. As in *Mensing*, Allergan could not use the CBE regulation to independently add a black box warning or similar prominent warning to the top of the BOTOX® label because that labeling change would have violated the sequence, format, and content requirements for prescription drug labeling. (*See* Supp. Br. at 1-13.) The only difference between this case and *Mensing* is **which** other federal law the labeling change would have violated.

Plaintiff makes three misguided arguments as to why *Mensing* does not apply to this case. First, Plaintiff argues that *Mensing* does not apply because "the statutory provision upon which *Mensing*'s central holding was based is inapplicable to brand-name drugs." (Supp. Response at 5.) It is true that the federal requirements at issue in *Mensing*—that generic labels match brand-name labels—did not prohibit Allergan from using the CBE regulation. But the legal principle of *Mensing*—that a manufacturer cannot use the CBE regulation to make a labeling change that violates other federal laws—still applies in this case because both the old and new federal regulatory requirements governing the content and format of prescription drug labeling did prohibit Allergan from adding any warning to the top of the BOTOX® label.

Second, Plaintiff contends that *Mensing*'s finding of preemption does not apply because *Mensing* reaffirmed the holding in *Wyeth* that brand-name manufacturers can use the CBE

regulation to unilaterally strengthen their warnings. (Supp. Response at 5.) But *Wyeth* does not establish the extraordinary proposition that brand-name manufacturers are free to ignore all federal drug labeling requirements when strengthening a warning through the CBE regulation. Indeed, the existence of a specific provision allowing manufacturers to "ask" the FDA in writing "to waive any requirement under §§ 201.56, 201.57, and 201.80," 21 C.F.R. § 201.58, makes clear that a manufacturer cannot use the CBE process to unilaterally make changes to its label that violate those requirements. Here, the changes Plaintiff claimed state law required—adding a black box warning or other prominent warning to the top of its label—conflicted with federal drug labeling requirements and were therefore impossible for Allergan to accomplish independently under federal law. (*See* Supp. Br. at 1-13.) Critically, *Wyeth* did not involve the same black box or prominent warning claims, and so did not involve the federal regulatory requirements preventing a manufacturer from independently adding such warnings.

Third, Plaintiff argues that "*Mensing* preserved the impossibility preemption framework of *Wyeth* and its application to brand-name manufacturers, who must show 'clear evidence' that the FDA would have rejected a stronger warning." (Supp. Response at 5-6.) That standard is wholly inapplicable here. *Wyeth* held that even if a manufacturer **could** use the CBE regulation to unilaterally change its label without prior FDA approval, the manufacturer could still establish impossibility preemption by presenting "clear evidence" that the FDA would have ultimately disapproved the labeling change. *See Wyeth*, 555 U.S. at 571. The Court explained in *Mensing* that even though the CBE regulation allowed Wyeth to independently strengthen its label, the FDA "retained the authority to eventually rescind Wyeth's unilateral CBE changes," so Wyeth "could have attempted to show, by 'clear evidence,' that the FDA would have rescinded any change in the label and thereby demonstrate that it would in fact have been impossible to do

under federal law what state law required." 131 S. Ct. at 2581 n.8. This is an **additional** way to establish impossibility—when (as in *Wyeth*) the CBE regulation is available. But there is no need to reach that **additional** basis for preemption when, as here (and in *Mensing*), the manufacturer could **not** have used the CBE regulation to unilaterally make the labeling change Plaintiff claims state law required. In that context, *Mensing* compels a finding of preemption.

## II. FDA Regulations, Including the CBE Regulations, in Effect in 2006 or 2007 Prohibited Allergan From Changing Its BOTOX® Package Labeling to Include a Prominent Warning (Not a Black Box Warning) Without Prior FDA Approval

As Allergan has consistently argued, Plaintiff's claim that Allergan was liable for failing to add a prominent warning is preempted because the old and new FDA labeling content and format requirements prohibited Allergan from independently adding a prominent warning to the top of its BOTOX® label in 2007. Moreover, Plaintiff's argument is also preempted because Plaintiff repeatedly conflated the concepts of a prominent warning and a black box warning throughout the trial, and both the old and new FDA labeling content and format requirements prohibited Allergan from unilaterally adding a black box warning to the BOTOX® label in 2007. (S*ee* Opening Br. at 4-8; Supp. Br. at 1-13.)

### A. Plaintiff's Substantive Responses Are Incorrect

Plaintiff responds by repeating the misguided argument that Allergan was required to present "clear evidence" that the FDA would have rejected a stronger warning. (Supp. Response at 6-7.) As explained, *see supra* at 4-5, the "clear evidence" standard does not apply because Allergan could not have used the CBE regulation to make the labeling change at issue.

Plaintiff next argues that the FDA regulations did not prohibit Allergan from adding a prominent warning to the top of its BOTOX® label. (Supp. Response at 7-11.) Plaintiff suggests that "neither the old-drug **nor** new-drug regulations controlled the Botox label in 2006-2007." (*Id.* at 8 n.3 (emphasis added).) That is incorrect. Whatever the better answer as to

**which** set of regulations applied, there is no basis to conclude that the labeling of prescription drug products was **completely unregulated** between June 30, 2006, when the new requirements were adopted, and the deadline by which a manufacturer had to submit a label conforming to the new requirements (sometimes years later). In any event, both the old **and** new labeling requirements prohibited the labeling change at issue. As to the old requirements, 21 C.F.R. §§ 201.56(e), 201.80, Plaintiff admits that "the regulations dictate that the section containing warnings be placed after several other sections." (*Id.* at 8.) And as to the new requirements, Plaintiff does not contest that the regulations dictate that the top of the label must be the FDA-pre-approved "Highlights of Prescribing Information" section and that the "Warnings and Precautions" section comes much later in the label, *see* 21 C.F.R. §§ 201.56(d)(1), 201.57(a).[3] Plaintiff's concession that Allergan could **not** have placed a warning "right up front" or "right up at the beginning" of the label without violating both the old and new requirements means that Plaintiff's claim is preempted under the analysis of *Mensing*.

Ignoring his own concession, Plaintiff contends that Allergan could have used the CBE regulation to add a prominent warning because "the CBE regulation included a single restriction on such changes—that the manufacturer cannot use the CBE 'to make any changes to the information required in § 201.57(a).'" (Supp. Response at 9.) This argument completely ignores *Mensing*. The restriction that prohibited the manufacturers from making the labeling change at issue in *Mensing* was not explicitly stated in the then-applicable CBE regulation. It was a

[3] With respect to the new labeling requirements, Plaintiff contends only that § 201.57(d)(1)'s requirement that "headings and subheadings" "must be highlighted by bold type that prominently distinguishes the headings and subheadings from other labeling information," 21 C.F.R. § 201.57(d)(1), does not prohibit manufacturers from using bold type for "other labeling information." (Supp. Response at 10-11.) Yet Plaintiff does not explain how one can use bold type to "prominently **distinguish[]**" between headings and "other labeling information"—if the "other labeling information" is also in bold type.

separate statutory and regulatory requirement that generic labels match brand-name labels. The CBE regulation did not authorize the manufacturers to violate that requirement.

Likewise, in this case, the old format and content requirements that prohibited Allergan from adding a warning at the top of its label were separate regulatory requirements that prohibited Allergan from making the labeling change at issue. The new labeling requirements similarly prohibited Allergan from adding a warning to the top of its label (and the CBE regulation itself prohibited Allergan from unilaterally changing the top of its label). Contrary to Plaintiff's suggestion, (*see* Supp. Response at 9), the CBE regulation is not "*carte blanche*" to ignore other federal regulatory requirements.

Plaintiff's argument that *Wyeth* "elevated the manufacturer's duty to maintain an adequate label, through the CBE or otherwise, above these types of secondary labeling concerns" is unsupported. (Supp. Response at 9 (citing *Wyeth*, 555 U.S. at 570).) Plaintiff cites a discussion in *Wyeth* where the Court concluded that the labeling change at issue **would not have violated** other federal regulatory requirements. *See Wyeth*, 555 U.S. at 570 ("But strengthening the warning about IV-push administration would not have made Phenergan a new drug. Nor would this warning have rendered Phenergan misbranded." (citations omitted)). But that discussion provides no support for Plaintiff's argument that the CBE regulation allows manufacturers to violate other federal regulatory requirements.

**B. A New Trial Is Necessary**

Plaintiff argues that even if his claim is preempted, a new trial is not necessary. First, Plaintiff suggests that because the jury was not instructed that Allergan was required to put its label "right up front," his claim is not preempted. Allergan has not contested that Plaintiff "could have tried his case on the general theory that Allergan was negligent in failing to

strengthen language **in the label's 'warnings and precautions' section**" using the CBE regulation. (Rule 59 Reply at 1 (emphasis added).) But that is not how Plaintiff tried the case. When the Court asked Plaintiff "Are you planning on using the black box issue?" he responded "Yes sir, I think I'm whetted [sic] to that. That's how I tried the case." (Trial Tr. 1518:6-11.) He continued that the testimony concerning black box warnings was "critical" to "whether the warning could be expected to catch the attention of a reasonable prescribing physician" and that "prominence in putting it in bigger type right at the beginning is the **crucial** part of our case." (Trial Tr. 1518:15-20 (emphasis added).) Plaintiff cannot now disavow his theory of the case and for the first time contend that Allergan could have changed the warnings section of the label to make the spread of toxin more prominent (Supp. Response at 9-10)—the **type** of prominent warning that Plaintiff repeatedly argued was required by state law is preempted.

Second, Plaintiff contends Allergan waived this preemption argument when it agreed that Instruction 26 could be given if Plaintiff did not argue for a black box warning. (Supp. Response at 11-13.) In the discussion of the jury instructions, the Court recognized that if Plaintiff was going to "use the black box part of it" then the jury would have to be instructed that "Allergan would have to have the approval of the FDA." (Trial Tr. 1521:5-11.) Plaintiff's counsel responded by proposing that if the Court did not give that instruction to the jury, he would not mention the black box warning in closing. (*Id.* at 1521:15-21.) He then asked whether he "could still make the argument about a prominent warning to catch the doctor's attention since it matches [Instruction No. 25]." (*Id.* at 1521:25-1522:3.) The Court responded: "I don't know why you couldn't say they could put it in bold letters or highlighted in red and have it printed that way **in the warnings part of it**." (*Id.* at 1522:4-7 (emphasis added).) Allergan's counsel then explained that "every single detail" of the label is regulated and expressed concern about

getting into a "semantic argument where they could have put a warning at the top of the label that was bold that was in [a] really dark square but we're not going to say black box." (*Id.* at 1522:9-17.) The Court responded: "That's not what I'm saying." (*Id.* at 1522:18.) Allergan understood this Court's comment to indicate that the Court agreed with Allergan's counsel that such semantic games would not be allowed. After this clarification, Allergan agreed that "if he does not argue the black box then we'll accept 26 as modified." (*Id.* at 1523:18-20.) Accordingly, Allergan's objection that Plaintiff violated this agreement and argued for the functional equivalent of a black box warning is not waived because Allergan's (and this Court's) understanding that Plaintiff would "not argue the black box" clearly encompasses the understanding that Plaintiff would not argue that the **functional equivalent** of a black box warning was required.

Nor did Allergan waive its preemption challenge to Plaintiff's claim that state law required a prominent warning at the top of the BOTOX® label. Rather, at most, Allergan agreed with the Court that Plaintiff could argue that Allergan should have revised "the warnings part" of the label, (*id.* at 1522:6-7), which Plaintiff now acknowledges must "be placed after several other sections" in the label. (Supp. Response at 8.) But Plaintiff's argument (at closing and throughout trial) was not limited to the warnings part of the label, and thus violated any agreement that such arguments were allowed. (*See, e.g.*, Trial Tr. 1559:24-1560:1 ("It should have been very **prominently displayed right up front in the label**, where no one could miss it."); *id.* at 1560:18-1561:4 ("Now, lets talk about the issue of **prominence**. . . . If you've got

something serious to warn them about, don't bury it in the fine print on page 3. **Put it right up front in big, bold letters. That's the law and they didn't do it.**")).[4]

Finally, Plaintiff attacks a straw man by arguing that even if his prominent warning claim is preempted, it "does not warrant preemption of Plaintiff's entire case." (Supp. Response at 13.) Allergan has not argued that it does. This argument pertains to Allergan's motion for a new trial, not a motion for judgment as a matter of law. Plaintiff relies on *Schedin v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, No. 08-5743, --- F. Supp. 2d ---, 2011 WL 3837104 at *14 (D. Minn. Aug. 26, 2011), for the proposition that even if federal law "applied to preempt 'one theory of the claim, it would not foreclose punitive damages on other alleged bases.'" (Supp. Response at 13.) That was the basis for the court's denial of the defendant's motion for judgment as a matter of law, *see Schedin*, 2011 WL 3837104 at *14, which would have been appropriate only if "no reasonable juror could return a verdict for the nonmoving party," *id.* at *12. The court explicitly noted that "[m]otions for judgment as a matter of law must meet standards that are more stringent than the standards applied to motions for a new trial." *Id.* *Schedin* therefore has no application here, where the centerpiece of the Plaintiff's case was a preempted theory and thus requires a new trial.

As Allergan explained (Supp. Br. at 17-18), when one theory of liability is proper and the other is not, the "court must remand the case for a new trial unless it is 'reasonably certain that the jury's verdict was not influenced by the erroneously-submitted . . . theor[y].'" *Harwood v. Partredereit AF 15.5.81*, 944 F.2d 1187, 1193 (4th Cir. 1991). Plaintiff contends this principle

[4] Plaintiff's counsel further violated the agreement not to discuss a black box warning by gesturing to the jury in the shape of box when discussing the necessary warning. (*See* Opening Br. at 18 n.14 (describing video).) Plaintiff's counsel does not deny making these gestures but instead contends "there was no intention to use hand gestures to suggest a black box warning." (Supp. Response at 12-13.) But counsel's actions, not his asserted intent, are what matter. Regardless of his intent, the prejudice to Allergan from the undisputed gestures is the same.

does not apply when "the jury is properly instructed" and "one of several factual bases argued by the plaintiff . . . is faulty." (Supp. Response at 13-14.)[5] This distinction between factual theories and causes of action does not mean preemption has no force. The Supreme Court has recognized that just as one of multiple causes of action can be preempted, one of multiple factual bases undergirding a single cause of action can be preempted. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 524-25 (1992) (plurality) (failure-to-warn cause of action preempted "to the extent" it relies on certain factual theories, but not on others); *see also Imperial Premium Fin., Inc. v. Khoury*, 129 F.3d 347, 352-54 (5th Cir. 1997) (remanding for a new trial because one of two factual bases underlying fraud cause of action was improper and since the verdict form "did not differentiate between the theories of fraud liability posited by plaintiffs, it is impossible for us to now determine whether or not the jury's verdict is legally sustainable"). Plaintiff's black box and prominent warning theories were central to his case and are preempted, so Plaintiff cannot prove to a reasonable certainty that the jury did not rely on them. A new trial is warranted.

## III. Plaintiff's Claims Are Preempted Regardless Of The Fact That Allergan Was Not Prohibited From Asking the FDA Whether It Could Add a Black Box Warning

As Allergan explained, the fact that it could have asked the FDA for permission to add a black box warning does not overcome the preemption of Plaintiff's claims. (*See* Supp. Br. at 13-14.) The Supreme Court explicitly held in *Mensing* that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." 131 S. Ct. at 2581. That holding directly controls here.

[5] As explained, *see supra* at 9-10, the jury was not properly instructed because it was not given the instruction necessary to cure Plaintiff's violation of the agreement not to discuss boxed warnings at closing.

Plaintiff contends that "the rationale for this holding was entirely based on the distinction between generic and brand-name manufacturers" because the FDA would have to approve the label change *and* negotiate with the brand-name manufacturer to implement the change. (Supp. Response at 15-16.) But the holding in *Mensing* is not so limited. As the Court explained, "[t]he question for 'impossibility' preemption is whether the private party could **independently** do under federal law what state law requires of it." *Id.* at 2579 (emphasis added). A party cannot "independently" comply with both federal and state law when all it can do is ask the federal government for permission to take the action required by state law. That is true regardless of whether the federal government could immediately grant permission or would have to consult with a third party before doing so.

The rationale for this rule is unrelated to the distinction between generic and brand-name manufacturers. The Court explained that if simply asking the federal government to "reinterpret its regulations" or to "rewrite its regulations" would "suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force." *Id.* Allergan's ability to ask the FDA for permission to add a black box warning (or other prominent warning) does not allow it to comply with a state law duty to actually add such a warning. Plaintiff's claims are preempted.

## IV. FDA Regulations in Effect in 2006 or 2007 Prohibited Allergan From Issuing, Without Approval of the FDA, in the United States, the Dear Doctor Letter That Was Issued in Europe

### A. FDA Regulations Prohibited Allergan from Issuing a Dear Doctor letter Containing "Substantial New Warning Information" Without Prior Approval

Plaintiff argued at trial that Allergan should have issued the European Dear Doctor letter in the United States because the July 2007 BOTOX® label did not adequately contain the warnings in that letter. (*See* Trial Tr. 1557:12-1558:16.) Plaintiff continues to argue that the

warnings in the European Dear Doctor letter were not included in the label. (Supp. Response at 19.)[6] As Allergan explained (Supp. Br. at 16-17), however, FDA regulations prevented Allergan from issuing a Dear Doctor Letter that included "substantial new warning information" because such letters must be "consistent with and not contrary to [the drug's] approved or permitted labeling." 21 C.F.R. § 201.100(d)(1). *See also Mensing*, 131 S. Ct. at 2576; Brief for United States as Amicus at *18-19, *Mensing*, 2011 U.S. S. Ct. Briefs LEXIS 282 (Mar. 2, 2011) (the Dear Doctor Letter "would have violated [§ 201.100(d)(1)] because its very purpose would have been to depart from what [Plaintiff] allege[s] was an insufficiently serious warning in the approved labeling.").

Plaintiff claims that "Allergan has failed to cite to . . . any FDA regulation restricting a brand-name manufacturer's ability to send a Dear Doctor Letter," (Supp. Response at 18), but that ignores § 201.100(d)(1). Plaintiff suggests that § 201.100(d)(1) applies only to generic drugs, but by its own terms it applies to a "drug subject to the requirements of [21 U.S.C. § 353(b)(1)]," § 201.100, and to "[a]ny labeling," § 201.100(d). Nothing in the text, history, or structure of § 201.100(d)(1) suggests that it applies only to generic drugs. Nor did the FDA or Supreme Court draw this distinction in *Mensing*. *See* Brief for United States as Amicus at *18-19, *Mensing*, 2011 U.S. S. Ct. Briefs LEXIS 282; *Mensing*, 131 S. Ct. at 2576.[7]

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[6] Allergan's position throughout has been that the substance of the warnings was very similar. (*See* Opening Br. at 10 n.6; Supp. Br. at 17.) But Plaintiff's argument that Allergan should have sent a Dear Doctor Letter with novel warning information, which the jury could have accepted, is preempted.

[7] The outdated guidance Plaintiff cites does not explain how a new warning issued only via a Dear Doctor Letter would be "consistent with and not contrary to" a package insert lacking that warning. *See* Labeling and Prescription Drug Advertising: Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37,434, 37,447 (June 26, 1979). Plaintiff never argued to the jury that Allergan should have first amended the warnings section of the U.S. package label under the CBE regulation as "permitted labeling" in order to issue the European Dear Doctor letter as "consistent with" that labeling. Any such argument is therefore waived.

### B. Regardless of Whether Allergan Could Have Issued the Dear Doctor Letter, the Verdict Must Be Reversed for a New Trial

Regardless of whether Allergan could have issued the European Dear Doctor letter, a new trial is necessary because Plaintiff's preempted theories prejudiced the jury's liability determination. *See Harwood*, 944 F.2d at 1193. As Plaintiff admitted, *see supra* at 8, the cornerstone of his case at trial was that Allergan should have added a boxed warning or other prominent warning at the top of the BOTOX® label. Those theories were preempted, and Plaintiff cannot establish that it is "reasonably certain that the jury's verdict was not influenced by the erroneously-submitted … theor[ies]." *Harwood*, 944 F.2d at 1193.

## V. Plaintiff's Closing Argument Violated the Rule Stated in *Leathers v. General Motors Corp.*

In opposing Allergan's argument that a new trial is required based on Plaintiff's counsel's improper use of a "Golden Rule" argument during closing, Plaintiff offers three primary arguments: (1) that Allergan failed to contemporaneously object; (2) that Plaintiff's counsel did not actually make a "Golden Rule" argument; and (3) that Allergan has not suffered any prejudice. Each of these arguments is without merit.

### A. The Fourth Circuit Does Not Require A Contemporaneous Objection

Citing cases from other circuits, Plaintiff contends that a new trial should not be awarded because Allergan's counsel failed to make a contemporaneous objection to Plaintiff's "Golden Rule" argument. The Fourth Circuit, however, does not require a contemporaneous objection in this context. *See Leathers v. General Motors Corp.*, 546 F.2d 1083 (4th Cir. 1976); *Werner v. Upjohn Co.*, 628 F.2d 848 (4th Cir. 1980). The "substantial justice" and "plain error" standards in cases from some other circuits cited by Plaintiff simply do not apply here.

In *Leathers*, the defendant did not make a contemporaneous objection to the plaintiff's improper "Golden Rule" argument, and did not accept the court's offer to admonish the jury to

disregard the argument. The Fourth Circuit nevertheless held that a new trial was required, noting that "[c]ounsel for defendant was placed in an unnecessarily difficult and embarrassing position. To interrupt argument by plaintiffs' counsel might antagonize the jury, and would certainly emphasize the point." 546 F.2d at 1086. In *Werner,* the Fourth Circuit confirmed the exception to the contemporaneous objection rule as recognized in *Leathers,* and extended it to statements made during closing in violation of Fed. R. Evid. 407:

> The defendant failed to object to the closing argument quoted above, but such an objection is not required in this circuit. *Leathers v. General Motors Corp.*, 546 F. 2d 1083 (4th Cir. 1976). In *Leathers* during closing argument plaintiff's counsel had invoked the "Golden Rule" argument which in essence, asked the jury to decide the case as they would want it decided if they were the plaintiff. Despite lack of objection to the argument we reversed and remanded for a new trial stating that the defendant was not required to make a contemporaneous objection because to do so might only have emphasized the impermissible point and have antagonized the jury.

628 F.2d at 854. In both *Leathers* and *Werner,* the Fourth Circuit recognized the Hobson's Choice inherent in such objections, so it did not require them. The rationale of those controlling cases is equally applicable here. Allergan was not required to contemporaneously object to Plaintiff's "Golden Rule" argument in order to preserve this objection.

### B. Counsel's Argument Was Plainly A "Golden Rule" Argument Made In The Context Of An Overall Appeal To Juror Sympathy

Plaintiff also argues that he did not make a "Golden Rule" argument, and that Allergan has taken his statements out of context. As support, Plaintiff cites Trial Transcript 1588:6-23, which he contends is the "extended transcript" providing the proper context for counsel's statements. (Supp. Response at 23.) Notably, however, Plaintiff's "extended transcript" fails to include the excerpt cited on page 20 of Allergan's Supplemental Memorandum, which provides:

> Can you imagine the horror when he first realized that something was terribly wrong. He couldn't walk right. He couldn't think right. Couldn't speak right.

> He's not going to be able to take care of his mother and his wife. His mother is going to have to go live somewhere else. Can you imagine?

(Trial Tr. 1586:20-1587:1). Plaintiff thus fails to address Allergan's argument that this excerpt, which immediately preceded the excerpt cited by Plaintiff (and which itself constitutes an improper "Golden Rule" argument), demonstrates that Plaintiff's counsel's overall intent during this segment of his closing argument was to appeal directly to juror sympathy.

Instead, Plaintiff again contends, just as he did in the initial Rule 59 briefing, that his use of the word "you" in this context "refers to Mr. Ray, not members of the jury," (Supp. Response at 23), even though (1) he repeatedly switched from using "he", "his", and "him" to using "you", (2) a nearly identical argument was rejected in *Leathers*, and (3) construing his "you" as referring to "Mr. Ray" leads to linguistically absurd results.[8] *See also Moody v. Ford Motor Co.*, No. 03-CV00784-CVE-PJC, 2007 U.S. Dist. LEXIS 44495, at *28 (N.D. Okla. June 18, 2007) (rejecting similar argument).

**C. Plaintiff's Improper Argument Impermissibly Taints The Verdict**

Plaintiff argues that use of a "Golden Rule" argument is not reversible error *per se,* and that Allergan has failed to show any evidence of "actual harm." (Supp. Response at 26.) But to find that a new trial is necessary, the Court need not find that each statement, taken individually, is so improper as to alone warrant a new trial. Rather, the court must examine "the totality of the circumstances." *See CSX Transp. v. Lone Star Indus. (In re Lone Star Indus.*), No. 93-1505, 1994 U.S. App. LEXIS 6957, at *26 (4th Cir. April 7, 1994) *See also Whitehead v. Food Max of Miss., Inc.*, 163 F.3d 265, 278 (5th Cir. 1998) ("That the awards were improperly influenced

[8] The implausibility of Plaintiff's contention can be illustrated by replacing the word "you" with "Mr. Ray": "I'll give [Mr. Ray] $12 million, [Mr. Ray] can forget the rest of [Mr. Ray's] life. [Mr. Ray's] just going to be in bed with brain damage. Do [Mr. Ray] think he would have made that trade? Do [Mr. Ray] think any reasonable person would? I don't." (Trial Tr. 1588:19-23.)

by passion and prejudice is indicated by their size. . . . This large verdict, when accompanied by counsel's improper arguments, further indicates that the jury was influenced by the prejudicial statements."); *Westbrook v. General Tire and Rubber Co.*, 754 F.2d 1233, 1241 (5th Cir. 1985) (a large verdict accompanied by improper appeals to local bias "leads us to conclude they had an influential impact on the jury's deliberations"); *Klotz v. Sears, Roebuck & Co.*, 267 F.2d 53, 54-55 (7th Cir. 1959) (ordering new trial based on improper statements by plaintiff's counsel even though the court had sustained objections to the statements and directed the jury to disregard them); *Cooper v. Miami-Dade Cnty.*, No. 01-976-CIV-JORDAN, 2004 U.S. Dist. LEXIS 17542, at *51-54 (S.D. Fla. July 9, 2004) (awarding new trial even though curative instruction had been given, noting that "[i]n an emotional trial. . . , composed primarily (if not exclusively) of circumstantial evidence, it would be erroneous to underestimate the impact of the "golden rule" argument on the issue of liability").

In this case, as set forth in Allergan's prior briefs, Plaintiff's counsel made numerous improper statements and direct appeals to juror sympathy during closing argument. (*See* Opening Br. at 38-40; Supp. Br. at 22-23.) In *Leathers*, the Fourth Circuit held that a new trial was necessary even though the offending argument was made during opening statements. 546 F.2d at 1085. Here, the offending arguments were made during closing, and therefore even more likely to directly impact juror deliberations than the improper argument in *Leathers*, particularly given the emotional nature of this case. Under these circumstances, the Court's fundamental duty "to protect the parties from unjust verdicts arising from impulse, passion, or prejudice, or from any other violation of lawful rights," *Norfolk & W. Ry. Co. v. Holbrook*, 235 U.S. 625, 630 (1915), dictates that Allergan be granted a new trial as to both liability and damages.

## VI. Plaintiff's Closing Argument Violated the Rule Stated in *Phillip Morris USA v. Williams*

In response to Allergan's argument that Plaintiff violated the rule set forth in *Phillip Morris v. Williams*, 549 U.S. 346 (2007). Plaintiff offers two primary arguments: (1) that *Williams* allows evidence of harm to others to be used to prove reprehensibility, and (2) that Allergan was not prejudiced because the jury's $200 million punitive damages award was reduced to the $350,000 statutory cap. Both arguments miss the mark.

First, although *Williams* does allow juries to consider evidence of actual harm to others in the context of evaluating reprehensibility, that does not authorize the jury to speculate about **potential** (rather than actual) harm to nonparties, which is what Plaintiff's counsel invited the jury to do.[9] Moreover, the Court violated *Williams* by failing to "provide assurance" by way of jury instruction that the jury was not using that evidence to punish Allergan for harm caused to others. 549 U.S. at 355.

Second, the fact that the jury's punitive damage award was subsequently reduced by the Court to the $350,000 statutory cap does not negate the prejudice resulting from the violation. The jury awarded $200 million in punitive damages, and there is a substantial likelihood that this award was based on emotion, passion, or prejudice driven by the jury's improper consideration of harm to nonparties. "[I]f there is reason to conclude that the jury's calculation of damages was substantially affected by emotion, there is also reason to question the jury's underlying assignment of liability." *Allred v. Maersk Line, Ltd.*, 826 F. Supp. 965, 970 (E.D. Va. 1993). Accordingly, "[w]here a damage award is the result of passion or prejudice (as opposed to

[9] Plaintiff's counsel invited jurors to "think of all the Douglas Rays in the United States that were being injected with BOTOX in 2007 for mild to moderate nonlife-threatening conditions," (Trial Tr. 1567:23-1568:4), but he did not offer any specific evidence that they suffered the BOTOX®-induced injury Plaintiff claims to have suffered or the amount of harm to that population. Such evidence would have provided some limit on the jury's consideration. Instead, the jury was left to speculate about potential harm.

miscalculation, for instance), the court must grant a new trial on *both* liability and damages." *Id.* (citing *Minneapolis, St. Paul & Sault Ste. Marie Ry. Co. v. Moquin*, 283 U.S. 520, 521 (1931)). *See also Filkins v. McAllister Bros., Inc.*, 695 F. Supp. 845, 852 (E.D. Va. 1988). Thus, merely reducing the damage award is not sufficient; the Court should also set aside the jury's tainted liability finding and order a new trial.

## CONCLUSION

For the reasons stated in Allergan's memorandum in support of its Rule 59 motion and in its supplemental briefing, a new trial is necessary.

Respectfully submitted,

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## Certificate of Service

I hereby certify that on the 20th day of January, 2012, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will then send notification of such filing to the following:

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